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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,846	03/06/2002	Michael A. Masini	MED-00205/29	9623

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EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,846

Applicant(s)

MASINI, MICHAEL A.

Examiner

Jackson J Suzette

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5-7,16,20 and 24-26 is/are allowed.
- 6) ☒ Claim(s) 3,4,8-11,17-19 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 12-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is improper antecedent basis for the “**score marks**”.
2. The disclosure is objected to because of the following informalities: On page 9, lines 8-9 the phrase does not make sense: “Note in Figure 4....than that shown in Figure 4....” Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: **All of the 500 series elements**. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
4. The drawings are objected to because there is no “**Brief Description**” of **Figure 5**. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
5. The drawings are objected to under 37 CFR 1.83(a) because they fail to show element “**320**” as described in the specification on page 7. Any structural detail that is essential for a

proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-4, 9-11, 17-19, 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 3, 10, 18 and 22 recites the limitation "the shoulder articulating joint surface corresponds to a humerus". There is insufficient antecedent basis for this limitation in the claim.

9. Claims 9, 17 and 21 recites the limitation "wherein the hip articulating joint surface".

There is insufficient antecedent basis for this limitation in the claim.

10. Claim 4, 11, 19, 23 recites the limitation "where in the knee articulating joint". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. 5,047,061 which discloses the invention as claimed comprising: a prosthetic element having an articulating joint surface and an intramedullary stem (see figure 4, 15 and 21); positioning apparatus for adjusting the orientation of the prosthetic element relative to the bone (10), the apparatus including: a feature that encircles at least a portion of the bone (col. 4 lines 44-47), a structural element (11, 26) to engage the cortex of the bone so as to rigidly but removeably couple the positioning apparatus to the bone and one or more fasteners (17b, 18b, 24) that may be loosened and tightened to adjust the position of the prosthetic element relative to the bone. The “intended use recitation/functional language “rigidly but removeably” and “that may be loosened and tightened to adjust the position” carries no patentable weight in the absence of any distinguishing structure. “Brown” clearly discloses the structure *as claimed* and is found to be inherently capable of performing the function.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 4,357,716. Brown has been disclosed above however Brown does not specify shoulder joint surfaces corresponding to a proximal humerus or knee articulating joint surface corresponding to a distal femur. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Brown and modify them to fit the humerus or knee articulating joint because both joints include stem and articulating surfaces and Brown teaches in col, 2 lines 20-25 that holding units adapted for holding and protecting prosthetic necks of different geometrical shapes are provided.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 8-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,267,785. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because patent 6,267,785 claims all of the features of the application (see claim 6 of '785). It is obvious to one having ordinary skill in the art at the time the invention was made that the subject matter is merely restated in a broader context.

Allowable Subject Matter

17. Claims 1-2, 5-7, 12-16, 20, and 24-26 are allowed.
18. Claims 3-4, 17-19 and 21-23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
19. Claims 12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
20. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Masini 6,379,391; Manasas et al. 6,371,991 ; Maroney et al. 6,277,123 ; Kasra et al.

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6,126,691 ; Burke 5,951,606 ; Garner 5,078,746 ; Eftekhar 4,404,692 ; and Brown 4,357,716 all show related material.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

23. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3580.

24. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J. Jackson', with a stylized, flowing script.

Suzette J. Jackson

03 April 2003